

REMARKS

Favorable consideration of this application is respectfully requested in view of the foregoing amendment and the following remarks.

Claims 1-16, 18-20, 22 and 29-31 are pending in the application. Claims 1-4, 19, 22 and 29-31 have been amended. Dependent claim 19 has been cancelled and replaced by independent claim 33. New claims 32-37 have been added. Support for the language in new claims 32-37 can be found in the specification, e.g., page 4, line 19 (claim 32); originally filed claim 19 (now claim 33); page 1, lines 29-30, page 11, lines 13-21, and page 5, lines 22-24 (claims 33-37). It is submitted that no new matter has been added.

Claims 1-16, 18-20, 22 and 29-31 have been rejected under 35 U.S.C. §112, first paragraph, based on an alleged lack of enablement. The Examiner contends that the specification, while being enabling for a salt of a compound of formula (I), does not reasonably provide enablement for a hydrate of a compound of formula (I).

To facilitate prosecution, claim 1 has been amended to delete the phrase “and/or hydrate form.”

In view of the above, withdrawal of the rejection of claims 1-16, 18-20, 22 and 29-31 under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claims 1-16, 18-20, 22 and 29-31 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner essentially contends that claim 1 recites “prodrug” and the present specification lacks a definition/example of the above term, and thus it does not convey to the skilled artisan in the art that at the time of filing applicant had possession of the claimed invention.

To facilitate prosecution, claim 1 is amended to delete recitation of the phrase "and/or prodrug."

In view of the above, withdrawal of the rejection of claims 1-16, 18-20, 22 and 29-31 under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claim 30 has been rejected under 35 U.S.C. §112, first paragraph, based on alleged lack of enablement. The Examiner contends that the instantly claimed invention is highly unpredictable because the skilled artisan in the art would recognize the differences in the etiology of the gynaecological disorders from cancer to bloating to hot flashes etc. and treatment thereof. The Examiner also contends that there is no evidence in the art of a single agent that is known to be effective in treating gynecological disorders in general. The Examiner also contends that in the absence of a showing of correlation between all gynaecological disorders and the effectiveness of the claimed compounds in treating the disorders, one of skill in the art would be unable to fully predict the effect of administration of the claimed compounds in the treatment of the disorders as encompassed by the instant claim.

In response, claim 30 has been amended to recite the specific gynecological disorders: endometriosis, dysmenorrhea, dysfunctional uterine bleeding and severe premenstrual syndrome. New claims 34-36 have also been added to recite these disorders and the specific disorder, endometriosis. Support for the recitation of the specific gynaecological disorders in amended claim 30 and new claims 34-36 can be found in the specification, e.g., at page 1, lines 29-30 and page 11, lines 13-21.

Applicants also submit that there is a correlation between the in vitro activity, i.e., progesterone receptor modulators (SPRMs), of the presently claimed compounds and their effectiveness in treating the specific gynaecological disorders recited in amended claim 30 and new claims 34-36. In this regard, the Examiner's attention is directed to Chwalisz et al., Selective Progesterone Receptor Modulators, Annals New York Academy of Sciences, Vol. 955, pp. 373-388, 2002 [Chwalisz et al., a copy of which is attached as Exhibit A.]. Chwalisz et al. indicate that

selective progesterone receptor modulators (SPRMs) may have use in the treatment of endometriosis and symptoms manifested by this disease such as dysmenorrhea and pelvic pain (see pp. 373-375 and 379-384). Accordingly, one skilled in the art would have a reasonable expectation that the presently claimed compounds as SPRMs also may have use in treating endometriosis and dysmenorrhea as recited in amended claim 30 and new claim 35. It is further submitted in view of the Chwalisz et al. disclosure on SPRMs and their endometrial antiproliferative effect (see page 379-384), and that SPRMs are implicated in dysmenorrhea and the control of uterine blood flow/the stabilization (prevention of unscheduled bleeding) of the endometrial vessels (see page 384, paragraph and page 385, last paragraph), one skilled in the art would have a reasonable basis to believe that the presently claimed compounds as SPRMs would also be useful in the treatment of the specific gynaecological disorders, dysfunctional uterine bleeding and severe premenstrual syndrome, recited in amended claim 30 and new claim 35.

In view of the above, withdrawal of the rejection of claim 30 under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claims 1-16, 18-20, 22 and 29-31 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite in the recitation of the term “prodrug” in claim 1.

To facilitate prosecution, claim 1 has been amended to delete the term “prodrug.”

In view of the above, withdrawal of the rejection of claims 1-16, 18-20, 22 and 29-31 under 35 U.S.C. §112, second paragraph, is respectfully requested.

A good faith effort has been made to place the present application in condition for allowance. If the Examiner believes a telephone conference would be of value, she is requested to call the undersigned at the number listed below.

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Attachment: Exhibit A

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